

REMARKS

Applicants have carefully reviewed the Office Action mailed on July 20, 2010. Applicants respectfully traverse all objections, rejections and assertions made by the Examiner. Claims 20-29 are pending.

Claim Rejections under 35 U.S.C. § 103

Claims 20-29 were rejected under 35 U.S.C. §103(a) as being unpatentable over Puno (US 5,360,431) in view of Mathews (US 6,033,406) and Foley (US 5,792,044) and Davison (US 2001/0011170). This rejection is respectfully traversed.

Puno appears to teach an open surgical procedure for performing a two-level spinal fixation:

Initially, the area of implantation is surgically approached. A longitudinal posterior midline incision is made over the spine. The incision is carried through the subcutaneous tissue and the fascia to the tips of the spinous processes. Subperiosteal dissection is performed over the laminae and transverse processes. The facet capsule and articular cartilage are removed in preparation for fusion.

See column 6, lines 50-57. The Examiner acknowledges that Puno fails to teach inserting an access device and performing their surgical procedures through an access device. Davison is asserted as teaching a method involving inserting an access device, actuating the access device to a second configuration having an enlarged cross-sectional area at the distal portion spanning at least a portion of the multiple vertebrae, and performing various surgical procedures, such as decompression and fixation procedures, through the access device. The Examiner appears to assert that it would have been obvious to one of ordinary skill in the art to perform the surgical procedure of Puno through the access device of Davison. Applicants respectfully disagree. Puno appear to teach an open surgical procedure for inserting 6 pedicle screws, 2 rods, and one or more cross-linking members, as shown in FIGS. 14-20. Davison teaches, "present invention is applicable to a variety of surgical procedures in which endoscopic surgical techniques are used." See paragraph [0017]. Davison also teaches, "[s]urgical instruments are inserted into the body during endoscopic surgery through the passage 16." See paragraph [0018]. Davison also teaches:

The expandable second tubular portion 40 of the cannula 10 provides a significantly larger working area for the surgeon inside the body 130 within the confines of the cannula. As a result, the simultaneous use of a number of endoscopic surgical instruments, including but not limited to steerable instruments, shavers, dissectors, scissors, forceps, retractors, dilators, and video cameras, is made possible by the expandable cannula 10.

See paragraph [0035]. Applicants submit that one of ordinary skill in the art, upon reading Puno and Davison, would have no rational reason for attempting to perform the multi-level spinal fixation of Puno through the device of Davison. Puno does not teach their surgical procedure as being endoscopic, thus the skilled person would have no rational reason to look to Davison for alternative devices to using an endoscope. The Examiner appears to be asserting that Davison teaches performing decompression and fixation procedures using their device, but the Examiner has not provided any indication of where in the reference this teaching is found. MPEP 2143.01 III states:

The mere fact that references can be combined or modified does not render the resultant combination obvious unless **>the results would have been predictable to one of ordinary skill in the art. *KSR International Co. v. Teleflex Inc.*, 550 U.S. ___, ___, 82 USPQ2d 1385, 1396 (2007)

Emphasis original. Applicants submit that attempting to performing the complex, open surgical procedure of Puno through the device of Davison would not have given predictable results. As discussed above, Davison appears to teach, “[s]urgical instruments are inserted into the body during endoscopic surgery through the passage 156.” See paragraph [0036]. In view of the teachings of Davison, Applicants submit that the only reason or motivation for one of ordinary skill in the art to attempt to perform the procedures of Puno through the device of Davison is found in Applicants’ specification, which is an error. The Examiner appears to be relying on Applicants’ disclosure and hindsight rather than the actual teachings of the references, in order to make a determination of obviousness. Applicants submit there is nothing in Puno to suggest or lead one of ordinary skill in the art to attempt to perform their open procedure of inserting multiple screws, rods, and cross-linking members through a device described as allowing passage of endoscopic instruments. Neither Matthews nor Foley appear to provide any rational reason or motivation for modifying Puno as asserted by the Examiner.

In the Response to Arguments section of the final Office Action on page 5, the Examiner states that, "[u]nder the TSM Test a claimed invention is obvious when there is a teaching, suggestion, or motivation to combine prior art teachings and has no requirement for establishing predictable results." The Examiner appears to be acknowledging that there is no predictability in combining Puno, Davison, Matthews, and Foley, and is thus not relying on the KSR arguments. The Examiner appears to be relying solely on the TSM test, rather than the tests set forth in the KSR decision. The Examiner further states, "examiner has provided the differences between the prior art references and the claimed invention and has provided a teaching reference with a motivation for one having ordinary skill in the art to combine the prior art teachings as required by the TSM Test (MPEP 2141)." Applicants respectfully disagree. As discussed above, Puno appears to teach an open surgical technique for inserting 6 pedicle screws, 2 rods, and one or more cross-linking members, as shown in FIGS. 14-20. Davison, however, appears to teach that, "the simultaneous use of a number of endoscopic surgical instruments, including but not limited to steerable instruments, shavers, dissectors, scissors, forceps, retractors, dilators, and video cameras, is made possible by the expandable cannula 10." See paragraph [0035]. Davison thus appears to provide motivation, if at all, for one of ordinary skill in the art to perform an endoscopic procedure involving multiple instruments, through their device instead of an endoscope. Puno does not appear to teach an endoscopic procedure, and the Examiner has not asserted that Puno is related to endoscopic procedures. The asserted teaching, suggestion, or motivation provided by Davison does not appear to be related to the type of procedure taught by Puno. One of ordinary skill in the art, upon reading Puno and Davison, would not have seen any teaching, suggestion, or motivation for attempting to use the device of Davison, taught as an advantage for endoscopic procedures, in the open surgical procedure of Puno. Taking into account only knowledge that was within the level of ordinary skill at the time the claimed invention was made, and not including Applicants' disclosure, there is no teaching, suggestion or motivation for the skilled artisan to attempt the open surgical procedure of Puno using the device of Davison. Applicants submit the missing part of the Examiner's argument using TSM is some teaching, suggestion, or motivation in a reference that the open surgical procedure of Puno could be performed endoscopically. The cited references fail to provide such a teaching, suggestion, or motivation. The rejection is thus an error. Reconsideration and withdrawal of the rejection are respectfully requested.

Conclusion

Reexamination and reconsideration are respectfully requested. It is respectfully submitted that all pending claims are now in condition for allowance. Issuance of a Notice of Allowance in due course is requested. If a telephone conference might be of assistance, please contact the undersigned attorney at (612) 767-4574.

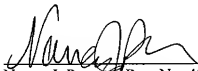
Respectfully submitted,

Alan Shluzas et al.

By their Attorney,

Date: _____

9/20/10



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